§ 10.19 Waiver, suspension, or modification of procedural requirements.

The Commissioner or a presiding officer may, either voluntarily or at the request of a participant, waive, suspend, or modify any provision in parts 12 through 16 applicable to the conduct of a public hearing by announcement at the hearing or by notice in advance of the hearing if no participant will be prejudiced, the ends of justice will thereby be served, and the action is in accordance with law.

Subpart B—General Administrative Procedures

§ 10.20 Submission of documents to Division of Dockets Management; computation of time; availability for public disclosure.

(a) A submission to the Division of Dockets Management of a petition, comment, objection, notice, compilation of information, or any other document is to be filed in four copies except as otherwise specifically provided in a relevant FEDERAL REGISTER notice or in another section of this chapter. The Division of Dockets Management is the agency custodian of these documents.

(b) A submission is to be signed by the person making it, or by an attorney or other authorized representative of that person. Submissions by trade associations are also subject to the requirements of § 10.105(b).

(c) Information referred to or relied upon in a submission is to be included in full and may not be incorporated by reference, unless previously submitted in the same proceeding.

(1) A copy of an article or other reference or source cited must be included, except where the reference or source is:

(i) A reported Federal court case;

(ii) A Federal law or regulation;

(iii) An FDA document that is routinely publicly available; or

(iv) A recognized medical or scientific textbook that is readily available to the agency.

(2) If a part of the material submitted is in a foreign language, it must be accompanied by an English translation verified to be complete and accurate, together with the name, address, and a brief statement of the qualifications of the person making the translation. A translation of literature or other material in a foreign language is to be accompanied by copies of the original publication.

(3) Where relevant information is contained in a document also containing irrelevant information, the irrelevant information is to be deleted and only the relevant information is to be submitted.

(4) Under § 20.63 (a) and (b), the names and other information that would identify patients or research subjects are to be deleted from any record before it is submitted to the Division of Dockets Management in order to preclude a clearly unwarranted invasion of personal privacy.

(5) Defamatory, scurrilous, or intemperate matter is to be deleted from a record before it is submitted to the Division of Dockets Management.

(6) The failure to comply with the requirements of this part or with § 12.80 or § 13.20 will result in rejection of the submission for filing or, if it is filed, in exclusion from consideration of any portion that fails to comply. If a submission fails to meet any requirement of this section and the deficiency becomes known to the Division of Dockets Management, the Division of Dockets Management shall not file the submission but return it with a copy of the applicable regulations indicating those provisions not complied with. A deficient submission may be corrected or supplemented and subsequently filed. The office of the Division of Dockets Management does not make decisions regarding the confidentiality of submitted documents.

(d) The filing of a submission means only that the Division of Dockets Management has identified no technical deficiencies in the submission. The filing of a petition does not mean or imply that it meets all applicable requirements or that it contains reasonable grounds for the action requested or that the action requested is in accordance with law.

(e) All submissions to the Division of Dockets Management will be considered as submitted on the date they are postmarked or, if delivered in person during regular business hours, on the